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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

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10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,155	THOMBRE, AVINASH G.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 08/03/2007 are acknowledged.

2. Claim 12 was amended.

3. Claims 1, 3-22, and 24-27 are included in the prosecution.

Response to Arguments

Objection to claim 12

4. Applicant's correction of the typographical error in claim 12 is acknowledged. The objection of 5/3/07 is withdrawn.

Rejection of claims 1, 6-11 under 35 USC § 103(a)

5. Applicant's arguments, see Page 7, filed 08/03/2007, with respect to the rejection of claims 1, 6-11 under 35 USC § 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556) have been fully considered but are not persuasive.

Applicant argues that Lundy does not teach coating the particles to achieve sustained release and provides no indication of how such formulations could be prepared. Lundy teaches "microencapsulated formulations of the active ingredient, which may then be incorporated into a tablet, capsule, or other final formulation" (Page 14, lines 26-27). One skilled in the art of pharmaceutical product development would know that microencapsulated formulations of active ingredients are used for controlled or sustained or delayed release. Sparks is used as a supporting reference that teaches coated microparticles for controlled release (Col. 5, lines 51-64).

Applicant argues that the coating method of Sparks is not the same as that of the applicant and uses the analogy of the composition of Sparks being "peanut brittle" versus the "candied peanuts" of the applicant's invention. However, Sparks teaches: "...a) forming a solution of the polymer or polymers in a solvent; b) dissolving or dispersing the active ingredient in said polymer solution to form an uniform mixture; and removing the solvent from the mixture to obtain micro-particles having an average size of from 0.1 to 125μm" (Col. 5, lines 55-63). This clearly implies that what is obtained in Sparks is not "peanut brittle" but "candied peanuts". Therefore, the combination of Lundy and Sparks leads to the applicant's composition.

Therefore, the rejection of 5/3/07 is maintained.

Rejection of claims 1, 13-17 under 35 USC § 103(a)

6. Applicant's arguments, see Page 7, filed 08/03/2007, with respect to the rejection of claims 1, 6-11 under 35 USC § 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Jans et al. (US 5,824,336) have been fully considered but are not persuasive.

Applicant argues that Jans does not provide any teaching about controlled release or microparticles and that the combination of Lundy and Jans does not lead to the applicant's invention. However, Lundy teaches "microencapsulated formulations of the active ingredient, which may then be incorporated into a tablet, capsule, or other final formulation" (Page 14, lines 26-27). Jans is used as a supporting reference to provide the teaching of palatability-improving agents.

Therefore, the rejection of 5/3/07 is maintained.

Rejection of claims 1, 13-17 under 35 USC § 103(a)

7. Applicant's arguments, see Page 7, filed 08/03/2007, with respect to the rejection of claims 1, 6-11 under 35 USC § 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556) and further in view of Jans et al. (US 5,824,336) have been fully considered but are not persuasive.

Applicant argues that nowhere in the combination of Lundy, Sparks and Jans is there a teaching of coated microparticles and that these references taken together do not lead to the applicant's invention. However, as mentioned above Lundy teaches "microencapsulated formulations of the active ingredient, which may then be incorporated into a tablet, capsule, or other final formulation" (Page 14, lines 26-27). Sparks teaches: "...a) forming a solution of the polymer or polymers in a solvent; b) dissolving or dispersing the active ingredient in said polymer solution to form an uniform mixture; and removing the solvent from the mixture to obtain micro-particles having an average size of from 0.1 to 125μm" (Col. 5, lines 55-63). Jans is used as a supporting reference to provide the teaching of palatability-improving agents. Therefore, the combination of references provides a controlled release microencapsulated formulation with an active ingredient (as taught by Lundy), coating materials for microparticles (as taught by Sparks), and palatability-improving agents (as taught by Jans), which make the instant invention obvious. Since all the claimed elements are found in Lundy, Sparks and Jans, one skilled in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Applicant argues that, with regard to claims 18 and 19, it would not be routine experimentation to find the proper coating percentage and level of the palatability-improving agent. This is not found persuasive because one skilled in the art of pharmaceutical product development would try various types and levels of palatability-improving agents (given the teaching of Jans) in order to optimize the palatability or taste masking of the active ingredient during the process of routine experimentation. This process involves testing the palatability in subjects and modifying the formulation accordingly.

Applicant argues that, with regard to claims 20 and 21, the selection of a NSAID would not have been obvious over Lundy, the coating agents would not have been obvious over Lundy in view of Sparks, and the palatability-improving agents would not have been obvious over Jans. The selection of a NSAID would have been obvious over the NSAID carprofen taught by Lundy. Since all the claimed elements are found in Lundy, Sparks and Jans, one skilled in the art could have combined the elements and the combination would have yielded predictable results.

Applicant argues that, with regard to claim 22, the limitation of a dosage form suitable for administration to a dog or a cat would not have been obvious over Lundy, the coating agents would not have been obvious over Sparks, and the palatability-improving agents would not have been obvious over Jans. Since all the claimed elements are found in Lundy (NSAIDs for treating inflammation in dogs), Sparks and Jans, one skilled in the art could have combined the elements and the combination would have yielded predictable results.

Applicant argues that, with regard to claims 24-25, the process to prepare the composition would not have been obvious over Lundy in view of Sparks and Jans. Instant claim 24, lines 5-6 state "coating said particles with a delayed release, sustained release or pulsatile release material in an amount of about 5% to about 100% by weight of the pharmaceutical composition". This does not indicate how the particles are coated. Sparks teaches the process for preparing the controlled release microparticles (Col. 5, lines 51-64). Therefore, the method of making the composition would have been obvious to one skilled in the art.

Applicant argues that, with regard to claims 26 and 27, the limitations on the coating percentage would not have been obvious over Lundy in view of Sparks and Jans. Since Sparks teaches the process for coating the microparticles, the limitations on the coating percentage would have been obvious to one skilled in the art because during the process of routine experimentation, one would try different coating percentages in order to optimize the controlled release profile of the active ingredient.

Therefore, the rejection of 5/3/07 is maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556).

The claimed invention is a palatable, chewable, controlled release pharmaceutical composition for oral administration to a companion animal comprising a therapeutically effective amount of a pharmaceutically active agent (in controlled release multiparticulate form having coated particles with an average particle size of up to about 5000μm) and a palatability-improving agent (in an amount sufficient to make the pharmaceutical composition palatable to the companion animal).

Lundy et al. (WO 98/50033) teach chewable oral tablets comprising carprofen for treating pain and inflammation in dogs. This reference discloses "a solid peroral dosage form selected from the group consisting of delayed-release oral tablet, ... multiparticulates, ... sustained release oral tablets, ... and a chewable form in which said active ingredient is consumed along with the palatable chew, or may alternatively be delivered by leaching from the body of the chew which is not consumed, during mastication by the dog being treated ... microencapsulated formulations of the active ingredient ... may be incorporated into a tablet" (Page 14, lines 15-27). Dosage forms suitable for dogs such as tablets are disclosed, along with pharmaceutical excipients and adjuvants, which create a delayed, sustained, or controlled release of the active ingredient (Page 34, lines 4-12).

Lundy does not expressly teach the coating materials for the multiparticulate form.

Sparks teaches the coating materials for a controlled release powder comprising coated microparticles, which allow a sustained release of the active ingredient (Abstract and Col. 3, lines 15-17). Sparks teaches polymers suitable for coating including hydroxypropyl methyl cellulose, ethyl cellulose, cellulose acetate phthalate (Col. 3, lines 46-52), acrylates, methacrylates, and methacrylic polymers (Col. 4, lines 6-8).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the coating materials suggested by Sparks and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the coating materials allows a sustained release of the active ingredient (Sparks, Col. 3, lines 15-17).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 1, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Jans et al. (US 5,824,336).

The teaching of Lundy is stated above.

Lundy does not expressly teach the palatability-improving agents.

Jans teaches chewable tablets for companion animals comprising an active agent, excipients and palatability-improving agents. This reference teaches compositions containing large amounts of brewer's yeast (Col. 1, lines 66-67), flavoring agents "present in an amount from 0.001% to 0.5% by weight", and meat flavors as the preferred flavoring agents (Col. 2, lines 56-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the flavoring and palatability-improving agents suggested by Jans and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the flavoring and palatability-improving agents enhances palatability and consequently acceptance of the composition (including the active ingredient) by the companion animal.

11. Claims 1, 18-22, 24-27are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556), and further in view of Jans et al. (US 5,824,336).

Lundy does not expressly teach the coating materials for the multiparticulate form or the palatability-improving agents.

The teaching of Sparks regarding the coating materials is stated above.

The teaching of Jans regarding the palatability-improving agents is stated above.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the coating materials suggested by Sparks, and the flavoring and palatability-improving agents suggested by Jans, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the coating materials allows a sustained release of the active ingredient and using the palatability-improving agents enhances taste masking and acceptance by the companion animals.

Regarding instant claims 18 and 19, the limitation of coating percentage and palatability-improving agent percentage in the composition would have been obvious to one skilled in the art because these parameters are modified during the process of routine experimentation in order to optimize the release rate and taste masking.

Regarding instant claims 20 and 21, the limitation of the active agent being an NSAID (carprofen) would have been obvious over the carprofen taught by Lundy. The coating polymers would have been obvious over Lundy, in view of the coating agents taught by Sparks, and further in view of the palatability-improving agents taught by Jans.

Regarding instant claim 22, the limitation of the dosage form suitable for administration to a dog or cat would have been obvious given the peroral tablet formulations taught by Lundy (Page 14, lines 15-27), in view of the coating agents

taught by Sparks, and further in view of the palatability-improving agents taught by Jans.

Regarding instant claims 24-25, the process limitations for preparing the composition would have been obvious given the controlled release compositions taught by Lundy, in view of the coating polymers and process of preparing the controlled release composition taught by Sparks, further in view of the palatability-improving agents taught by Jans. One skilled in the art would vary the coating on the particles, modify the taste masking or palatability-improving agents in order to optimize the release rate and palatability, and form the composition into a suitable platform such as a chewable tablet to enhance acceptability by the companion animal.

Regarding instant claims 26-27, the limitations of coating percentage in the coated particles would have been obvious to one skilled in the art given the teaching of the controlled release composition by Lundy, in view of the coating materials and process taught by Sparks, and further in view of the palatability-improving agents taught by Jans.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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